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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/732,091	12/07/2000	Jing-Hui Tian	71515-198	3097

35161 7590 11/01/2005

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EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 11/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	Application No. 09/732,091	Applicant(s) TIAN ET AL.	
	Examiner Ginny Portner	Art Unit 1645	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 10/17/05 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: _____.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached..
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☒ Other: attachment alignment + article + Response to Remarks

Response to Arguments

1. Applicant's arguments filed October 17, 2005 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 112

1. The claim rejection under 35 USC 112, second paragraph for the recitation of the term "effective amount" is traversed on the grounds that the term is defined at page 5, lines 31-35 of the instant Specification which teaches "Methods of inducing an immune response to Helicobacter spp and methods of preventing, treating or ameliorating disorders or diseases related to Helicobacter in a mammal, in need of such treatment comprising administering an effective amount of the pharmaceutical or vaccine composition of the invention."

2. It is the position of the examiner that the instant Specification does not provide an explicit definition of the phrase "effective amount" and the claims do not require the amount of the polypeptide of the claims, to be a therapeutic, or protective amount to achieve the induction of an immune response that prevents, treats or ameliorates disorders or diseases. No specific amount is recited in the claims, because what the amount is, based upon the recited function is still unclear; what the composition is effective for, is not claimed.

Claim Rejections - 35 USC § 102

3. The rejection of claims 79,80, 82,83,84,86 under 35 U.S.C. 102(b) as being anticipate by Tomb et al (August 9, 1997) is traversed on the grounds that "Applicant is not claiming the Helicobacter genome, but are narrowly claiming one (1) single coding region for the use in a vaccine due to its unexpected immunogenicity.

4. It is the position of the examiner that the rejection of record was set forth under 35 USC 102(b) and remarks directed to unexpected immunogenicity are not convincing. Each of the polypeptides disclosed by Tomb et al were considered to be single coding regions, and the amino the nucleic acids that encode them were deposited in the EMBL database. Each Helicobacter pylori polypeptide was considered as a single entity, though the entire genome was sequenced. The polypeptide was cloned and expressed recombinantly in an E.coli attenuated laboratory strain of bacteria. The E.coli host cell did not express the entire H.pylori genome of 1590 coding sequences, just the polypeptide encoded by a nucleic to produce the amino acid sequence of SEQ ID NO 4. All claims, which recite the term "vaccine", are being read as composition claims that comprise the recited components, the *intended use* being one of a vaccine.

5. Applicant asserts that Tomb et al does not disclose vaccines.

6. The examiner agrees, but a recited intended use of a known polypeptide composition, does not impart patentable characteristics to the known composition. A new "Use" for a known composition may be patented in a method claim. None of the pending claims are directed to methods of treating, preventing or ameliorating disorders or diseases associated or caused by Helicobacter pylori infection. The claimed compositions are described and disclosed by Tomb et al who disclose an Helicobacter pylori polypeptide that shares 100% sequence identity (see alignment attached herewith) with the polypeptide of the claims. The amino acid structure of the polypeptide is 100% identical to the polypeptide instantly claimed, and would therefore inherently evidence the functional characteristics discovered by Applicant. Discovery of new functional characteristics for a known product does not define a patentable product, but claims

directed to a method which defines a new use for a known product could possibly define patentable subject matter. Atlas Powder Co. V IRECA, 51 USPQ2d 1943, (FED Cir. 1999) states Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art. However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art functioning, does not render the old composition patentably new to the discoverer. AThe Court further held that Athis same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art.

Additionally, it is the position of the examiner that Tomb et al isolated individual open reading frames, cloned them and expressed the polypeptides for the purpose of better understanding "a human pathogen, our interest in its biology and evolution, and the value of complete genome sequence information for drug discovery and vaccine development" (see Tomb et al, page 539, col. 1, paragraph 3). The claimed polypeptides were described by Tomb et al to be conserved protein.

7. The rejection of claims 85 and 88 under 35 U.S.C. 103(a) as being unpatentable over Tomb et al as applied to claims 79-80, 82-84, and 86 above, in view of WO96/40893 (1996) is traversed on the grounds that there is no suggestion or motivation in either reference or in the knowledge available to one of ordinary skill in the art to combine the teachings of Tomb et al and WO96.

8. It is the position of the examiner that Tomb et al describe a composition that comprises an HP30 polypeptide which has the amino acid sequence of SEQ Id NO 4, the polypeptide

having been recombinantly expressed, the composition comprising one or more additionally immunogens associated with the host cell E.coli, but differs from the instantly claimed invention by failing to show the polypeptide together with a pharmaceutically acceptable carrier and one or more adjuvants.

WO96' suggests, teaches and provides guidance for the formulation of polypeptide containing compositions that further comprise a pharmaceutically acceptable carrier and an adjuvant (see WO96' pages 84-85) because WO96' teaches the importance of inducing an immune response to a known human pathogen known to be associated with severe disease, wherein induction of an immune response to the compositions results in the attainment of an antibody reagent for diagnostic and therapeutic purposes (see page 2, lines 18-19 and page 85, lines 37-39 and first paragraph on page 86) and Tomb et al teaches the importance of producing recombinant polypeptides for the purpose of drug discovery and eventual vaccine development.

W096 teaches compositions that comprise Helicobacter polypeptides together with a pharmaceutically acceptable carrier and an adjuvant (see page 84, lines 26-34) and Tomb et al and WO96' are both directed to the formulation of compositions that will serve to induce an immune response which can serve as a tool for gaining greater insight into the pathogenesis of H.pylori (see WO96', page 83, paragraphs 2-4), as well as vaccine development (see Tomb et al, page 539, col. 1, last line; see WO96' abstract) and WO96' teaches through incorporating the Helicobacter polypeptide in an effective amount (see WO96', page 84, last paragraph, first line) into a composition that comprises both a carrier to protect the antigen (see WO96' page 85, lines 32-33) from acidic environments and an adjuvant to obtain an enhanced immune response to the

polypeptide, an immunogenic composition can be readily obtained. Tomb et al in view of WO96' (alignment provided herewith) still obviate the instantly claimed invention.

Conclusion

9. No claims are allowed.

1. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
October 27, 2005

L. F. Smith

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Attachment

O 26107

30	92	7.2	1939	2	T18372	repeat organellar
31	91.5	7.2	399	2	G72253	RNA polymerase sig
32	91.5	7.2	472	2	A64320	PET112 homolog - M
33	91.5	7.2	508	2	T24622	hypothetical prote
34	91.5	7.2	615	2	S42797	rad 26 protein - f
35	91.5	7.2	1769	2	S53378	probable membrane
36	91.5	7.2	1847	2	E64477	replication factor
37	91	7.1	284	2	A45488	body-wall muscle t
38	91	7.1	359	2	AI2368	hypothetical prote
39	90.5	7.1	320	2	B97214	hypothetical prote
40	90.5	7.1	1017	2	D90550	vsaa-like (mycopla
41	90.5	7.1	1411	2	T18417	hypothetical prote
42	90.5	7.1	1417	2	T18418	hypothetical prote
43	90	7.0	404	1	S03849	ribonucleoprotein
44	89.5	7.0	280	2	A72046	conserved hypothet
45	89.5	7.0	280	2	F86578	CT671 hypothetical

#HP1588

ALIGNMENTS

RESULT 1
D64718
conserved hypothetical protein HP1588 - Helicobacter pylori (strain 26695)
C;Species: Helicobacter pylori
C;Date: 09-Aug-1997 #sequence_revision 09-Aug-1997 #text_change 08-Oct-1999
C;Accession: D64718
R;Tomb, J.F.; White, O.; Kerlavage, A.R.; Clayton, R.A.; Sutton, G.G.; Fleischmann, R.D.
Peterson, S.; Loftus, B.; Richardson, D.; Dodson, R.; Khalak, H.G.; Glodek, A.; McKenne
son, J.D.; Kelley, J.M.; Cotton, M.D.; Weidman, J.M.; Fujii, C.; Bowman, C.; Watthey, L.
Nature 388, 539-547, 1997
A;Authors: Wallin, E.; Hayes, W.S.; Borodovsky, M.; Karpk, P.D.; Smith, H.O.; Fraser, C.
A;Title: The complete genome sequence of the gastric pathogen Helicobacter pylori.
A;Reference number: A64520; MUID:97394467; PMID:9252185
A;Accession: D64718
A;Status: preliminary; nucleic acid sequence not shown; translation not shown
A;Molecule type: DNA
A;Residues: 1-253 <TOM>
A;Cross-references: GB:AE000656; GB:AE000511; NID:g2314771; PIDN:AAD08627.1; PID:g231477

Query Match 100.0%; Score 1279; DB 2; Length 253;
Best Local Similarity 100.0%; Pred. No. 4e-88;
Matches 253; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

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Qy          1 MAYKYDRDLEFLKQLESSDLLDLFEVLVPGKDGEKRHNEKLTSSIEYKRHGDDYAKYAER 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          1 MAYKYDRDLEFLKQLESSDLLDLFEVLVPGKDGEKRHNEKLTSSIEYKRHGDDYAKYAER 60

Qy         61 IAEELQYYGSNSPASPIKGEGVLYKEILCDVCDKLKVNYNKKTETTLIEQNMLSKILERS 120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         61 IAEELQYYGSNSPASPIKGEGVLYKEILCDVCDKLKVNYNKKTETTLIEQNMLSKILERS 120

Qy        121 LEEMDDEEVKEMCDELSIKNTDNLNRQALSAATLTLFKMGGPKSYQLAVIVANAVAKTIL 180
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        121 LEEMDDEEVKEMCDELSIKNTDNLNRQALSAATLTLFKMGGPKSYQLAVIVANAVAKTIL 180

Qy        181 GRGLSLAGNQVLTRTLSFLTGPVGWIITGVWTAIDIAGPAYRVTIPACIVVATLRLKTQQ 240
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        181 GRGLSLAGNQVLTRTLSFLTGPVGWIITGVWTAIDIAGPAYRVTIPACIVVATLRLKTQQ 240

Qy        241 ANGDKKSLQIESI 253
              |||||||||||||
Db        241 ANGDKKSLQIESI 253
```

RESULT 2
B71800
hypothetical protein jhp1494 - Helicobacter pylori (strain J99)
C;Species: Helicobacter pylori
A;Variety: strain J99
C;Date: 12-Feb-1999 #sequence_revision 12-Feb-1999 #text_change 08-Oct-1999
C;Accession: B71800
R;Alm, R.A.; Ling, L.S.L.; Moir, D.T.; King, B.L.; Brown, E.D.; Doig, P.C.; Smith, D.R.;